

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

In re Application of: Rice *et al.*

Application No. 10/017,323

Filed: December 13, 2001

For: BENZOYLALKYLINDOLEPYRIDINIUM
COMPOUNDS AND PHARMACEUTICAL
COMPOUNDS COMPRISING SUCH
COMPOUNDS

Examiner: Not yet assigned

Date: June 20, 2002



Art Unit: 1619

CERTIFICATE OF MAILING

I hereby certify that this paper and the documents referred to as being attached or enclosed herewith are being deposited with the United States Postal Service on June 20, 2002 as First Class Mail in an envelope addressed to: BOX MISSING PARTS, COMMISSIONER FOR PATENTS, WASHINGTON, D.C. 20231.


Stacey C. Slater
Attorney for Applicant

BOX MISSING PARTS
COMMISSIONER FOR PATENTS
WASHINGTON, D.C. 20231

DECLARATION OF STACEY C. SLATER

Dear Sir:

Stacey C. Slater, having personal knowledge of the facts set forth below, declares as follows:

1. I have been informed that embodiments of the invention claimed by the referenced application were conceived and reduced to practice by the inventors while Drs. William Rice, Mingjun Huang, Robert Buckheit Jr., David Covell, Christopher Michejda and Grzegorz Czerwinski were employed by the National Institutes of Health (NIH) of Bethesda, Maryland, and while Dr. Vadim Makarov was employed by Gram Limited of Moscow, Russia.
2. I prepared the present application, No. 10/017,323, which was filed on December 13, 2001. The application was filed without signature.
3. Based on information received from the inventors, I understand that the compound referred to in method claim 7 as filed with the referenced application was submitted

to the NIH for biological testing by Dr. Makarov. I further understand, based on information received from Dr. Makarov by e-mail, that he selected the compound for submission to the NIH for biological testing, synthesized a sample and submitted it to the NIH for testing. The compound had been synthesized previously, apparently by Mrs. Svetlana Ryabova, but the structure of the compound itself is not being claimed in the present application. Although Dr. Makarov had not received the results of the biological analyses performed by one or more of the coinventors named on this application, a reasonable assumption is that he considered the compound biologically active upon submission to the NIH, and further that a method for exploiting the biological activity of such compound had been conceived by Dr. Makarov prior to such compound being submitted to the NIH for biological testing. In view of my understanding of the facts of this matter, and the holding by the Federal Circuit in *Burroughs Wellcome v. Barr Laboratories Inc.*, 32 USPQ2d 1915 (Fed. Cir. 1994), it appears that Dr. Makarov should be named as a coinventor of the application referenced above.

4. Dr. Makarov stated that he would not participate in a United States patent application, apparently because it might cause some personal hardship. The nature of this hardship has never been entirely clear, primarily as a result of the language barrier.

4. On April 15, 2002, Devon Zastrow of our firm sent a cover e-mail, an attached copy of the referenced application, a Combined Declaration and Power of Attorney, and an Assignment to Dr. Makarov at his last known e-mail address, *makar-cl@ropnet.ru*. A copy of our firm's letter and the e-mail is attached to this Declaration.


6. On April 16, 2002, Dr. Makarov replied by e-mail, stating, without correction:

I am not invertor (sic) of this work. Please exclude me from list of inventors. As I informed NIH early I can not sing (sic) the Combined Declaration and Power of Attorney, and the National Institutes of Health (NIH) has prosecute (sic) the application without my participation.

A complete copy of Dr. Makarov's reply e-mail message is attached.

Respectfully submitted,

KLARQUIST SPARKMAN, LLP

By 
Stacey C. Slater
Registration No. 36,011

One World Trade Center, Suite 1600
121 S.W. Salmon Street
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Telephone: (503) 226-7391
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Devon Zastrow

From: Devon Zastrow
Sent: Monday, April 15, 2002 10:44 AM
To: 'makar-cl@ropnet.ru'
Cc: 'HuS@OD.NIH.GOV'; Stacey Slater
Subject: BENZOYLALKYLINDOLEPYRIDINIUM COMPOUNDS AND PHARMACEUTICAL COMPOSITIONS COMPRISING SUCH COMPOUNDS

Importance: High

April 15, 2002

VIA E-MAIL ONLY (to makar-cl@ropnet.ru)

No confirmation copies will follow

Re: New U.S. Utility Application
For: BENZOYLALKYLINDOLEPYRIDINIUM COMPOUNDS AND
PHARMACEUTICAL COMPOSITIONS COMPRISING SUCH COMPOUNDS
First Inventor: Rice
NIH (DHHS) Ref No. E-091-01/1
Our Ref No: 4239-61858

Dear Dr. Makarov:

Please see the attached letter regarding the referenced U.S. utility patent application. A copy of the application as filed is attached, along with a Combined Declaration and Power of Attorney. If you decide to sign the attached Combined Declaration and Power of Attorney and proceed with the U.S. application, please sign and add your address using blue ink. As explained in the letter, if you do not sign the Combined Declaration and Power of Attorney, the National Institutes of Health (NIH) likely will prosecute the application without your participation.

Also attached is an Assignment, which if signed would formally convey your rights in this invention to the NIH. If you believe you have a duty to assign your rights in this invention to the NIH, or if you wish to do so, please sign and date the Assignment in blue ink. Your signature on the Assignment is not required to prevent the referenced patent application from going abandoned.

Please let us know how you intend to proceed concerning signing these documents by replying to this e-mail by **April 24, 2002**. If we do not hear from you by this date, we will assume that you will not sign the attached documents, and the NIH will proceed without your participation.

Let us know if you have any questions concerning how to execute the attached documents.

Stacey C. Slater, J.D.
Devon J. Zastrow, J.D.

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This e-mail contains confidential and/or privileged information intended only for the addressee. If you have received this communication in error, please call us collect at 503-226-7391 and ask to speak to the sender. Also, please notify the sender via e-mail that you have received the communication in error.



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**Not a Member of the Oregon Bar*

CONFIDENTIAL

May 17, 2002

Via Email Only to makar-cl@ropnet.ru

No Confirmation Copies Will be Sent

RE: New U.S. Utility Patent Application
For: BENZOYLALKYLINDOLEPYRIDINIUM COMPOUNDS AND
PHARMACEUTICAL COMPOSITIONS COMPRISING SUCH
COMPOUNDS

First NIH Inventor: Rice
Filed December 13, 2001
NIH (DHHS) Ref. No. E-091-01/2
Our Ref. No. 4239-61858

Dear Dr. Makarov:

We are intellectual property counsel representing the National Institutes of Health (NIH) to prosecute the referenced United States utility patent application. We understand, from our previous e-mail correspondence, and from information provided by the NIH, that you may not be allowed to claim and/or assign your rights in this invention, nor participate in the prosecution of any patent applications filed that are directed to this invention. While we understand your situation, the NIH has instructed us to continue to seek protection of its intellectual property.

Attached is a copy of the application as filed by the NIH. Please acknowledge receipt of this correspondence by return e-mail.

You were named as an inventor on the U.S. application based upon our understanding of the facts concerning the conception and reduction to practice of the claimed invention. In the United States, inventors are required to sign a Declaration stating that the inventor has read and understood the application, including the claims, as filed. The inventors also need to provide

Dr. Vadim Makarov
Our Ref. No. 4239-61858
May 17, 2002
Page 2

Power of Attorney to those representing the inventors before the United States Patent and Trademark Office. Attached is a Combined Declaration and Power of Attorney for your review.

Please review the U.S. utility application and the Combined Declaration and Power of Attorney. After you have completed your review, please (1) sign the document, stating that you have read and understood the application as filed, and granting us Power of Attorney to prosecute these applications on your behalf, or (2) let us know that you cannot or will not sign, such as by return e-mail.

In the United States, C.F.R. § 1.47 allows an inventor to continue prosecution of an application if a co-inventor refuses to sign. Therefore, if you refuse to sign the documents required for the United States application, the remaining inventors can, and likely will, prosecute this application unless instructed otherwise by the National Institutes of Health.

We must file the Combined Declaration and Power of Attorney with the United States Patent Office to respond to a Missing Parts Notice that will soon issue concerning the U.S. utility application. Therefore, please reply to this letter at your earliest convenience.

In addition, you should know that the NIH filed a Patent Cooperation Treaty (PCT) application directed to this invention on December 13, 2001, but has decided not to prosecute this application. Therefore, the PCT application will go abandoned in due course for failure to prosecute. This likely will mean that patent protection for the invention claimed in this PCT will be forfeited for countries other than the United States.

We remind you that we do not represent you as a client. We represent the NIH. As such, you should seek the advice of separate intellectual property counsel if you have any questions concerning your rights in this matter.

Sincerely,

KLARQUIST SPARKMAN, LLP

Stacey C. Slater

SCS/DJZ:kam

cc: Sally Hu, Ph.D., M.B.A.
William D. Noonan, M.D.
Devon J. Zastrow, Esq.

Dr. Vadim Makarov
Our Ref. No. 4239-61858
May 17, 2002
Page 3



Devon Zastrow

From: Makarov Vadim [makar-cl@ropnet.ru]
Sent: Tuesday, April 16, 2002 2:21 AM
To: Devon Zastrow
Subject: Re: BENZOYLALKYLINDOLEPYRIDINIUM COMPOUNDS AND
PHARMACEUTICAL COMPOSITIONS COMPRISING SUCH COMPOUNDS

Importance: High

Dear Mr. Zastrow,

I am not inventor of this work. Please exclude me from list of inventors. As I informed NIH early I can not sign the Combined Declaration and Power of Attorney, and the National Institutes of Health (NIH) has prosecute the application without my participation.

Sincerely Yours
Dr. VadimMakarov

At 11:43 15-04-02 -0700, you wrote:
April 15, 2002

VIA E-MAIL ONLY (to makar-cl@ropnet.ru)
No confirmation copies will follow

Re: New U.S. Utility Application
For: BENZOYLALKYLINDOLEPYRIDINIUM COMPOUNDS AND
PHARMACEUTICAL
COMPOSITIONS COMPRISING SUCH COMPOUNDS
First Inventor: Rice
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Let us know if you have any questions concerning how to execute the attached documents.

Stacey C. Slater, J.D.

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